

EXHIBIT D

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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

TAKEDA PHARMACEUTICAL
COMPANY LIMITED, TAKEDA
PHARMACEUTICALS NORTH
AMERICA, INC., TAKEDA
PHARMACEUTICALS LLC,
TAKEDA PHARMACEUTICALS
AMERICA, INC., and ETHYPHARM,
S.A.,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS USA
INC. and CADILA HEALTHCARE
LIMITED,

Defendants.

CIVIL ACTION NO:
3:10-CV-01723-JAP-TJB

**TO BE FILED UNDER SEAL
CONTAINS HIGHLY
CONFIDENTIAL-ATTORNEYS'
EYES ONLY INFORMATION**

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION
TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE ALL
TESTIMONY AND EVIDENCE RELATING TO ALLEGEDLY
NEW AND UNTIMELY DISCLOSED PRIOR ART REFERENCES**

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Pursuant to the Court's February 20, 2013 Order establishing deadlines for the submission of Pretrial Motions, Defendants, Zydus Pharmaceuticals USA Inc. and Cadila Healthcare Limited (collectively "Zydus") respectfully submit this Memorandum of Law in Opposition to Plaintiffs' February 28, 2013 Motion *In Limine* to Preclude all Testimony and Evidence Relating to Allegedly New and Untimely Disclosed Prior Art References. In further support of its Objection, Zydus also submits the March 7, 2013 Declaration of Vincent P. Rao, II, Esq. (the "Rao Decl.") and the exhibits attached thereto.

SUMMARY OF THE ARGUMENT

Plaintiffs' argue that Zydus is seeking to inject new invalidity theories into the case shortly before the commencement of trial, falsely implying that Zydus failed to comply with its prior disclosure obligations. Plaintiffs admit, however, that they "do not even know Zydus's supposed new invalidity theories with respect to the New References" that Zydus is purportedly attempting to inject into the case at the last minute. In other words, Plaintiffs are admitting they do not actually know that Zydus plans to offer the challenged references for purposes of proving invalidity.

Indeed, Plaintiffs entire motion is disingenuous because Plaintiffs failed to tell this Court that they were specifically informed by Zydus's counsel that Zydus is not utilizing these challenged references, either alone or in combination, as proof

or evidence of the invalidity of United States Patent No. 5,464,632 (the “‘632 Patent”).

Plaintiffs are perfectly well aware that Zydus only intends to offer the challenged references at trial with Dr. Byrn for entirely proper purpose of impeachment and/or to refresh recollection, neither of which limited purpose requires that Zydus have previously disclosed these references to Plaintiffs as part of its previously-served Invalidity Contentions.

Plaintiffs’ contention that Zydus should be precluded from utilizing the references at issue during cross-examination of Plaintiffs’ secondary considerations expert is wholly disingenuous and inconsistent with positions previously taken by Plaintiffs. The references at issue were previously utilized at the deposition of Plaintiffs’ secondary considerations expert on the ‘632 Patent in September 2012, and go directly, at the very least, to the issue of “long felt unmet need.” The fact that Plaintiffs did not move to preclude these references in its prior motions *in limine* served in September 2012, despite their knowledge as to Zydus intended use of them at this time, is only further proof positive that Plaintiffs’ present challenge is just a tactical move to hamper Zydus.

As a side note, although unfortunately an important one, it appears that Plaintiffs’ primary motive in filing this motion *in limine* is to use it as a vehicle to once again falsely disparage Zydus and its counsel in an attempt to poison the

proverbial well. Undoubtedly Plaintiffs believe “assassination by association” works, and if one says something enough times, however false, others will eventually come to believe it due to sheer repetition. Thus, while it would be Zydus’ strong preference to take the high road and simply ignore Plaintiffs’ baseless *ad hominem* attacks, the reality is that Zydus must take issue with them to insure that the long-term pattern of Plaintiffs falsely criticizing and attacking Zydus does not somehow subtly influence the Court, simply given the sheer volume of its repetition.

Thus, Plaintiffs’ motion *in limine* should be denied in all respects.

BACKGROUND

On August 31, 2012 Plaintiffs’ served the Rebuttal Expert Report of M. Brian Fennerty, M.D. focused on issues of secondary considerations. Dr. Fennerty was deposed on September 24, 2012. During his deposition Zydus’s counsel introduced as an exhibit each of the documents Plaintiffs now seek to exclude *in limine* as exhibits 1-6. *See* September 24, 2012 testimony of M. Brian Fennerty, at pgs. 34-37 and 40-48, Ex. B to the Rao Decl. The exhibits were introduced primarily to demonstrate that solid dosage forms which could disintegrate in the mouth in less than 60 seconds were known prior to the filing date of the application that led to the '632 Patent , *Id.* at 53(5-22), an issue that goes directly to secondary considerations, the very matters on which Dr. Fennerty has opined.

Trial in this matter was previously scheduled to begin on November 5, 2012.

The parties filed motions *in limine* on September 28, 2012 in anticipation of the November trial date. Notably, Plaintiffs did not move *in limine* to preclude the introduction of the references introduced at the Fennerty deposition. Thus, at a minimum the references Plaintiffs seek to exclude would have been proffered by Zydus at trial had trial been conducted in November 2012 as scheduled.

Prior to the November 5, 2012 trial, [REDACTED]

[REDACTED]

[REDACTED]. October 23, 2012 Sealed Order [Doc. No. 265]. [REDACTED]

[REDACTED], Plaintiffs served a Supplemental Expert Rebuttal Report (“Supplemental Report”) of Stephen Byrn, Ph.D. In his Supplemental Report, Dr. Byrn opines that:

[REDACTED]

Dr. Byrn was deposed on February 20, 2013. During his deposition Zydus’s counsel introduced the same prior art references that were introduced at Dr. Fennerty’s deposition. These prior art references were introduced for two

purposes: to impeach and rebut Dr. Byrn's position in his Supplemental Report regarding [REDACTED]

[REDACTED] and to refresh Dr. Byrn's recollection as to the state of the art of orally disintegrating tablets at the time of the filing of the '632 Patent. Again, Zydus' counsel made it clear that the references were not being introduced as invalidating prior art:

[REDACTED]

February 20, 2013 deposition of Stephen Byrn, at 154 (21-24), Rao Decl. Ex. A.

Despite the fact that Plaintiffs are aware that Zydus only intends to utilize the references at issue for wholly proper cross-examination purposes which do not necessitate disclosure as part of Zydus's Invalidity Contentions, Plaintiffs filed this wholly unnecessary motion *in limine*, and utilize it as a vehicle to once again falsely accuse Zydus and its counsel of playing "dirty pool."

ARGUMENT

POINT I.

Zydus Does Not Intend to Offer the References that Plaintiffs Seek to Exclude as Invalidating Prior Art Concerning United States Patent No. 5,464,632

A. The Challenged References Are Admissible to Impeach or Rebut the Testimony of Plaintiffs' Invalidity Expert

Plaintiffs' motion *in limine* is based entirely on the faulty premise that Zydus intends to utilize the references Plaintiffs' seek to exclude as invalidating prior art. That is not the case. Zydus recognizes that this Court's Local Patent Rules require the disclosure of invalidating prior art early on in a case. Zydus is not using the references at issue to show any element of the claims of the '632 Patent. Instead, Zydus will utilize the references to impeach and rebut expected testimony of Plaintiffs' expert. Zydus expects Plaintiffs' invalidity expert to opine that [REDACTED]

*February 12, 2013 Supplemental Report of Stephen Byrn,
at ¶11, Rao Decl. Ex. C.*

The references are intended to impeach and rebut this testimony.

FED. R. CIV. P. 26(a), which Plaintiffs' contend mandates that a failure to produce information precludes its use at trial, clearly states that evidence which is to be used solely for impeachment purposes need not be produced as part of discovery:

In addition to the disclosures required by Rule 26(a)(1) and (2), a party must provide to the other parties and promptly file the following information about the evidence that it may present at trial other than solely for impeachment.

FED. R. CIV. P. 26(a)(3).

This action was commenced in April 2010. At that time this Court's Local Patent Rules required Zydus to serve Invalidity Contentions, but did not require Plaintiffs to serve any contentions related to validity or otherwise respond to Zydus's Invalidity Contentions. (Compare December 23, 2008 District of New Jersey Local Patent Rules, Rule 3.6, with March 18, 2011 Amended District of New Jersey Local Patent Rules, Rule 3.6(i) requiring service of "Responses to Invalidity Contentions" by the patentee). Zydus did not even learn of Plaintiffs' theories rebutting Zydus's fully disclosed invalidating prior art until Plaintiffs'

served their Rebuttal Expert Report on August 31, 2012, which at that point was a mere two months before the than scheduled trial date.

This Court's Local Patent Rules did not, and do not as amended, require Zydus to seek leave to amend its Invalidity Contentions more than two years after they were initially served, in August 2010, in order to permit Zydus to offer evidence to impeach and rebut the opinions of Plaintiffs' invalidity expert. Of course, if Zydus had sought leave to amend its Invalidity Contentions, as Plaintiffs suggest Zydus should have done, Plaintiffs certainly would have vehemently objected to the amendment, claiming that it was too late and highly prejudicial.

Thus, under Plaintiffs' theory, Plaintiffs' expert could not be impeached with anything other than the references disclosed in Zydus's Invalidity Contentions. This is not the law. *See* FED. R. EVID. 607 ("Any party, including the party that called the witness, may attack the witness's credibility."); FED. R. EVID. 803(18) (making statements in learned treatises, periodicals, or pamphlets admissible for purposes of impeaching an expert witness); *Furey v. Temple Univ.*, 884 F. Supp. 2d 233, 252 (E.D. Pa. 2012) ("The purpose of cross examination is to ensure that issues of credibility and truthfulness are made clear to decision makers."); *Carnegie Mellon Univ. v. Marvell Tech. Group, Ltd.*, No. 09-290, 2012 WL 5451495, at *3 (W.D. Pa. Nov. 7, 2012), quoting *U.S. v. Lowe*, 234 F.2d 919,

922 (3d Cir. 1956) (“No authority needs to be cited for the proposition that one of the purposes of cross-examination is to test the credibility of the witness . . .”).

Plaintiffs’ view is also inconsistent with this Court’s own form of Final Pretrial Order which provides:

9. . . . EXHIBITS (Except for exhibits the need for which could not reasonably have been foreseen or which are used solely for impeachment purposes, only the exhibits set forth on the exhibit list attached hereto may be introduced at trial.

Form of Final Pretrial Order for, *inter alia*, the Honorable Joel A. Pisano, USDJ, at ¶9, emphasis added.

In addition, it is well settled that, on cross-examination, it is appropriate to question an expert witness with regard to his or her knowledge of other published materials in the relevant field. *See, e.g., Stottlemire v. Cawood*, 215 F. Supp. 266, 267 (D.D.C. 1963) (“It is the rule in the Federal courts that on cross-examination an expert witness may be interrogated concerning his knowledge of textbooks, treatises, articles, and other publications in his field, and that he may be confronted with extracts from them and asked whether he is familiar with them and whether he agrees with them.”); *see also Reilly v. Pinkus*, 338 U.S. 269, 275, 70 S. Ct. 110, 114, 94 L. Ed. 63 (1949) (“It certainly is illogical, if not actually unfair, to permit witnesses to give expert opinions based on book knowledge, and then deprive the party challenging such evidence of all opportunity to interrogate them about

divergent opinions expressed in other reputable books.”); *Dolcin Corp. v. F.T.C.*, 219 F.2d 742, 746-47 (D.C. Cir. 1954) (“[A]n expert witness who bases an opinion to a significant degree upon his reading may be cross-examined as to that opinion by reference to other reputable works in his field. It is not necessary for the witness to have relied in his testimony upon the particular authority the cross-examiner seeks to use.”).

Although Zydus is under no obligation to include documents to be used solely for impeachment purposes on its trial exhibit list, Plaintiffs would have the Court preclude Zydus from using these same documents unless they were disclosed in Zydus’s Invalidity Contentions. Indeed, if this Court’s Local Patent Rules limited Zydus’s ability to impeach and rebut Plaintiffs’ expert’s opinions concerning references cited by Zydus for obviousness and anticipation to only those references disclosed in Zydus’s Invalidity Contentions, there would be serious due process problems with this Court’s Local Patent Rules inasmuch as witnesses could simply skirt any invalidity argument by stating a non-rebuttable “fact” based on their experience. Thus, Plaintiffs’ Motion *in Limine* seeking to preclude references to be utilized by Zydus on cross examination for purposes of impeachment and rebuttal should be denied.

B. The Challenged References Are Admissible to Impeach or Rebut the Testimony of Plaintiffs' Secondary Considerations Expert

“A patent challenger bears the initial burden of demonstrating that the claimed invention is obvious to one of ordinary skill in the art.” *Convolve, Inc. v. Compaq Computer Corp.*, No. 00 Civ. 5141(GBD)(JCF), 2006 WL 2527773, *5 (S.D.N.Y., Aug. 31, 2006), citing *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir., 1986). “Subsequently, the burden shifts to the patentee to come forward with secondary indicia of non-obviousness . . . includ[ing] commercial success of the invention, failed attempts to develop the invention, and copying of the invention. *Id.*, citations omitted. *See also Braintree Labs., Inc. v. Novell Labs., Inc.*, No. 11-1341, 2013 WL 211252, at *15 (D.N.J., Jan. 18, 2013) (secondary considerations of non-obviousness include “whether there was long felt need for, or failure of others or unexpected results in the development of the claimed invention”).

On August 31, 2012 Plaintiffs served the expert report of M. Brian Fennerty, M.D. focused on issues of secondary considerations, disclosing for the first time Plaintiffs’ expert’s opinions related to secondary considerations of non-obviousness. Dr. Fennerty was deposed on September 24, 2012. During his deposition Zydus’s counsel introduced each of the documents Plaintiffs now seek to exclude *in limine* as exhibits. The documents were introduced primarily to demonstrate that there were references known prior to the filing of the application

that led to the '632 Patent that taught drugs in a solid dosage form that could be dissolved in the mouth in less than 60 seconds, an issue that goes directly to secondary considerations, the very matters on which Dr. Fennerty has opined.

Zydus was not required to disclose or include in its Invalidity Contentions the references it will use at trial to impeach or rebut Dr. Fennerty's testimony. Indeed, Zydus could not know the basis for Dr. Fennerty's opinions until his report was served, an event that did not occur until some two (2) years after Zydus served its initial Invalidity Contentions. Moreover, Plaintiffs could have made the decision to forego any expert testimony on secondary considerations, and Zydus could not know that Plaintiffs would offer a secondary considerations expert until the expert's report was served.

In addition, and significantly, Plaintiffs did not move to preclude the references following Dr. Fennerty's September 24, 2012 deposition even though the parties submitted pre-trial motions on September 28, 2012, in advance of the November 5, 2012. Plaintiffs failure to object to the references at that time constitutes an admission that the references are relevant to the issue of secondary considerations, and that Plaintiffs recognized that the references could be used at least for purposes of impeachment. Plaintiffs failure to timely object has prejudiced Zydus and Plaintiffs' Motion in *Limine* should be denied.

POINT II.

Plaintiffs Continue to Cast Aspersions on Zydus to Generally Poison the Well Against Zydus and Its Counsel

Plaintiffs are apparently unaware of the maxim:

When a man points a finger at someone else, he should
Remember that four of his fingers are pointing at himself ...¹

Plaintiffs disparagement of Zydus and its counsel throughout Plaintiffs' most recent filings comes as no surprise. Plaintiffs have been accusing Zydus of "flagrant violations of the Local Patent Rules," "flouting [the] local rules," litigation by "ambush," (see January 27, 2012 letter from John E. Flaherty to The Hon. Tonianne Bongiovanni), engaging in "gamesmanship," being "evasive," "scrub[bing]" its particle sizes, (see February 21, 2012 and Mach 12, 2012 Memoranda in Support of Plaintiffs' Motions for Spoliation Sanctions, filed under seal), "egregiously" seeking to insert "new invalidity opinions" into the case, (see September 28, 2012 Memorandum in Support of Plaintiffs' Motion *In Limine* to Preclude Expert Testimony on Invalidity Portions of The Rebuttal Expert Report By Dr. Harry Brittain, at 1), "drop[ping] a sandbag on evidence of infringement," having a "flagrant disregard for" and participating in a "continued effort to circumvent" the scheduling order (see October 12, 2012 letter from John E. Flaherty to the Hon. Joel A. Pisano, at 5 and 8), as well as "whitewash[ing] the

¹ Louis Nizer, Esq. (1902 – 1994), famed trial attorney and noted author.

case history” by providing the Court with a “misleading” rendering of the facts (*see*, October 18, 2012 letter from John E. Flaherty to the Hon. Joel A. Pisano, at 1 and 4).

Plaintiffs continued focus on Zydus and its counsel, rather than the merits of Plaintiffs own case, is telling. Indeed it is Plaintiffs that have a whole lot of “splainin” to do to the Court, as Ricky Ricardo often said to Lucy in the sitcom “I Love Lucy.” This is particularly true with regard to the explicit arguments made by Plaintiffs to the Court that the $\pm 10\%$ deviation they advocated for at Claim Construction was based on the error inherently associated with the accuracy of laser diffraction technology at the time of the invention,² which the Court clearly adopted as the basis of its construction ruling.³ Later testimony by Plaintiffs’ experts is particularly troublesome, given Plaintiffs’ disagreement with Zydus’s

² See statement of Arlene Chow at Markman Hearing, Markman Tr., at 50, Rao Decl., Ex. D : “The USP is what – the U.S. Pharmacopoeia sets a standard, persons of ordinary skill in the art understand **the level of accuracy of those instruments**, your Honor. . .”

³ See October 5, 2011 Opinion, p. 6-7 [Document 113], (emphasis added):

Defendants argue that the figure during the relevant time period was not 10%, but rather was less than 3%. *See* Def. Brf. at 10 (citing R. Xu, Particle Characterization: Light Scattering Methods (2002) at 166 (“... a modern commercial instrument should easily achieve a relative standard deviation less than 3% of the median value in repeat measurement...”). **However, the Court is not persuaded by such reference, as Defendants provide no basis for the Court to conclude that the state of the technology is such that its accuracy actually became worse over time.**

assertion that the deviation cited in the USP predominantly related to large batch sampling errors, and not instrumental error.⁴ Dr. Byrn testified [REDACTED]

[REDACTED]⁵ while Dr. Bugay testified that [REDACTED]

⁴ See, Markman Tr., at 37 (1-12) and 19-24), Rao Decl., Ex. D.:

MR. MOORE [Counsel for Zydus]: If I'm going back doing this, then the FDA says in your batches that you're making, we understand you may have wiggle room in your manufacturing, we're going to give you that ten percent. That's what it's saying. It's not talking about the granules themselves.

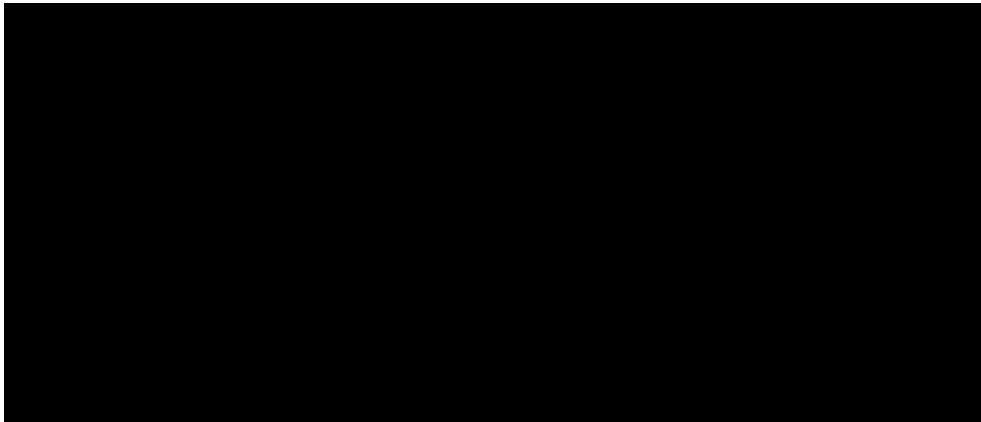
THE COURT: I don't know. You've got Dr. Byrn here in his deposition and he refers to paragraph 31 of his declaration and paragraph 31 of his declaration refers to paragraph 30 of his declaration, where he simply talks about the USP standard and the PQRI standards.

How is the inconsistent with anything?

* * *

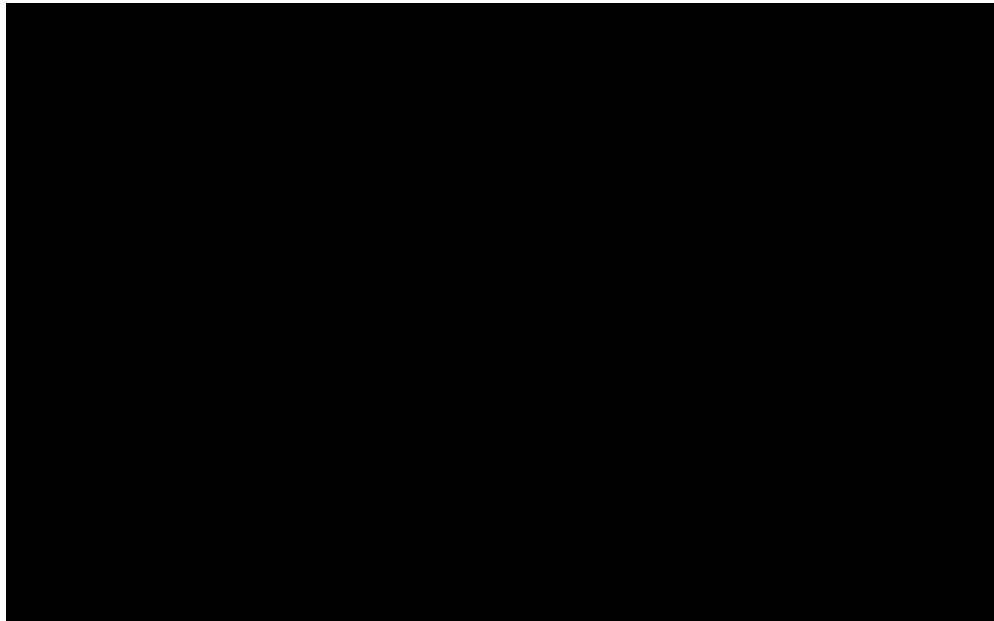
MR. MOORE: He's misquoting [the] USP.

⁵ See, February 20, 2013 Byrn Tr., at 53(23)-54(7), Rao Decl., Ex. A:

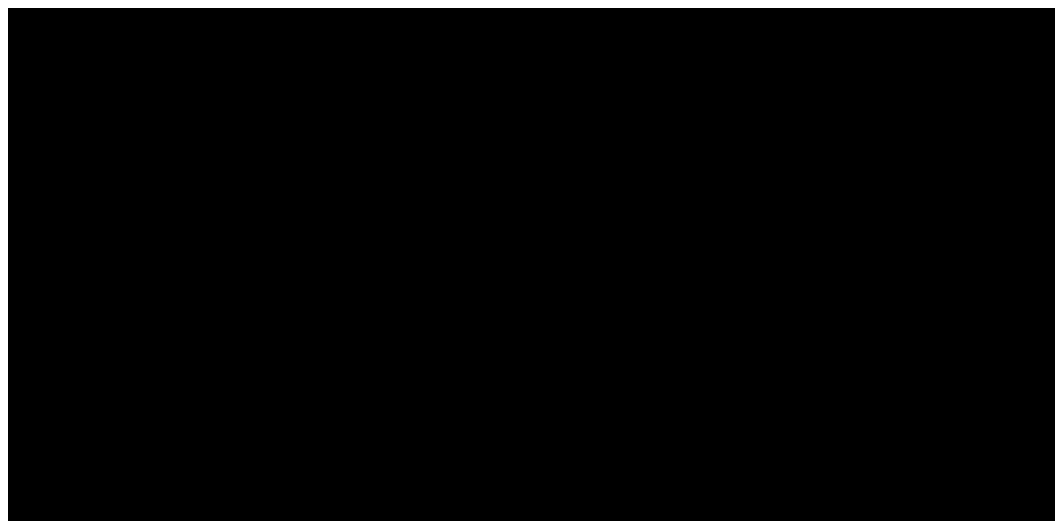


[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].⁷

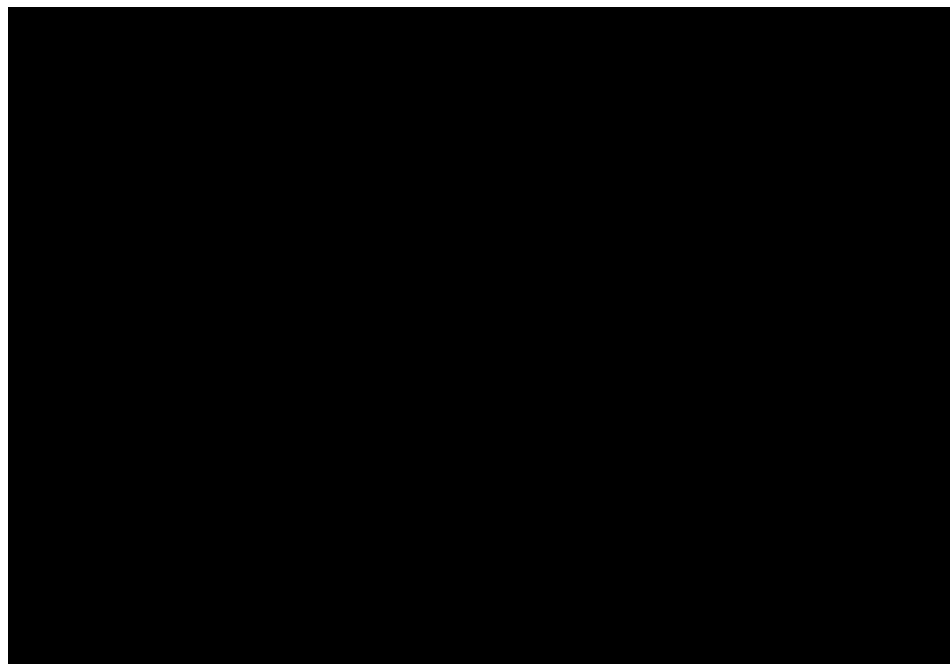
⁶ See, September 14, 2012 Bugay Tr., at 164(17)-165(6), Rao Decl. Ex. E:



⁷ See, February 22, 2013 Deposition Testimony of Dr. Harry Brittain, 178(18)-180(8), Rao Decl., Ex. F:



If Plaintiffs truly believed in the merits of the positions they have taken in this litigation, including the merits of the positions taken in this motion *in limine*, Plaintiffs would not have devoted so much of their time and energy disparaging Zydus and its counsel, and Zydus would not be compelled to respond. In short, as Shakespere put it in Hamlet, Act III, Scene II, one should look carefully at the motives of those that “protest too much.”



CONCLUSION

For all the foregoing reasons Plaintiffs' Motion *In Limine* to Preclude all Testimony and Evidence Relating to New and Untimely Disclosed Prior Art References should be denied.

Dated: March 7, 2013

KELLEY DRYE & WARREN LLP

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CERTIFICATE OF SERVICE

I hereby certify that on March 7, 2013 I caused to be served a copy of the foregoing Defendants Zydus Pharmaceuticals, USA, Inc. and Cadila Healthcare's Opposition to Plaintiffs' Motion *in limine*, and the accompanying Declaration of Vincent P. Rao submitted therewith, dated March 7, 2013, on each interested party in this action in accordance with the electronic filing procedures of the United States District Court for the District of New Jersey via ECF and email on the following.

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Dated: March 7, 2013

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